Atty Ref No.: 32286-192289

Appl. No.: 10/647,119

## **AMENDMENTS TO THE CLAIMS**

of claims will replace all prior versions and listings of claims in the application:

Claim 1 (cancelled).

Claim 2 (currently amended): The device of claim 11 [4], wherein the overcoat improves one or more properties of the device selected from echogenic coating durability, lubricity, surface smoothness, protection of the echogenic layer from deleterious effects of exposure to body fluids.

Claim 3 (currently amended): The device of claim 11 [4], wherein the structures are selected from the group consisting of pores, channels, cavities, pockets, and combinations thereof, covered by the overcoat.

Claim 4 (currently amended): The device of claim 11 [4], wherein the overcoat incorporates one or more pharmaceutical agents.

Claim 5 (currently amended): The device of claim 11 [1], wherein the overcoat layer reduces wettability so as to promote and/or prolong the entrapment of gas when the device is in the target medium.

Claim 6 (currently amended): A device according to claim 11, [4], wherein the overcoat layer has a thickness below about 2 microns.

Claim 7 (currently amended): A device according to claim 11, [4], wherein the overcoat layer has a thickness of between about 0.1 and about 1 micron.

Claim 8 (currently amended): A device according to claim 1, An ultrasonically visible solid device for inserting into a non-gas target medium, the device comprising an echogenic surface having structures entrapping gas causing the device to be ultrasonically visible, wherein the gas-entrapping structures are formed from open structures covered with a flexible overcoat layer that does not significantly reduce the compressibility of the gas trapped in the structures, and wherein the overcoat layer has a flexural modulus greater than about 500 psi.

Claim 9 (currently amended): A device according to claim 1 An ultrasonically visible solid device for inserting into a non-gas target medium, the device comprising an echogenic surface having structures entrapping gas causing the device to be ultrasonically visible, wherein the gas-entrapping structures are formed from open structures covered with a flexible overcoat layer that does not significantly reduce the compressibility of the gas trapped in the structures, and wherein the overcoat layer has an elongation at break greater than about 100 percent.

Claim 10 (currently amended): A device according to claim 11, [4] wherein the overcoat

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layer results in decrease he compressibility of less than about 20 percent of the entrapped gas bubbles.

Claim 11 (currently amended): A device according to claim 1 An ultrasonically visible solid device for inserting into a non-gas target medium, the device comprising an echogenic surface having structures entrapping gas causing the device to be ultrasonically visible, wherein the gas-entrapping structures are formed from open structures covered with a flexible overcoat layer that does not significantly reduce the compressibility of the gas trapped in the structures, and wherein the overcoat layer has a water permeability of less than about 10<sup>-10</sup>  $[(cm^3)(cm)]/(cm^2)(s)(cm Hg)].$ 

Claim 12 (currently amended): A device according to claim 11, [4] wherein the device is a stent, central venous catheter, peripherally inserted catheter, graft, shunt, percutaneous transcardiac arterial catheter, pacemaker, dialysis device, joint replacement, long term urinary device, tissue bonding urinary device, penile prosthesis, vascular catheter port, peripherally insertable central venous catheter, long term tunneled central venous catheter, peripheral venous catheter, short term central venous catheter, arterial catheter, PCTA or PTA catheter, and pulmonary artery Swan-Ganz catheter, guidewire, a surgical instrument, endoscopy equipment, an angioplasty balloon, a wound drain, a gastroenteric tube, laparoscopy equipment, a pellet, and an implant, a needle, and combinations thereof.

Claim 13 (currently amended): The device of claim 11 [4], wherein the overcoat comprises one or more of polyethylene, ethylene/vinyl acetate copolymers, epoxy resins, polydimethylsiloxane, polytetrafluoroethylene, polyvinylbutyral, polyvinylidinechloride, polyurethanes, polyimides, rubbers, acrylate polymers/copolymers, butadiene, styrene butadiene, and styrene butadiene/styrene copolymers.

Claim 14 (currently amended): The device of claim 11 [4], comprising an active agent selected from one or more of anti-thrombogenic agents, anti-inflammatory agents, antineoplastic agents, anti-proliferative agents, cytostatic agents, cytotoxic agents, antimicrobial agents, antirestenotic agents, anti-platelet agents, anti-coagulant agents, anti-fibrin and fibrinolytic agents, prostacyclins (and analogues), glycoprotein IIb/IIIa agents, thromboxane inhibitors, anti-thrombin agents, anti-mitotic, antiangiogenic and angiostatic agents, ACE inhibitors, growth factor antagonists, antioxidants, vitamins, calcium channel blockers, fish oil (omega 3-fatty acid), phosphodiesterase inhibitors, nitric acid donor, Somatostatin analogues, immunosuppresives and antiinflamatory agents, antimicrobials, radionuclides including alpha, beta and gamma emitting

isotopes, COX-2 inhibitors, endothelial promoters, kinase inhibitors, epidermal growth factor kinase inhibitors, tyrosine kinase inhibitors, MAP kinase inhibitors, and protein transferase inhibitors.

Claim 15: (currently amended): The device of claim 11 [4], comprising an active agent selected from one or more of plasmin, streptokinase, single chain urokinase, urokinase, t-PA (tissue type plasminogen activator), aminocaproic acid, aspirin, monoclonal antibodies, peptides, ReoPro, Cilastagel, eptifibatide, tirofiban, ticlopidine, Vapiprost, dipyridamole, forskolin, angiopeptin, argatroban, dextan, heparin, LMW heparin, Enoxaparin, Dalteparin, hirudin, recombinant hirudin, anti-thrombin, synthetic antithrombins, thrombin inhibitors, Warfarin, other coumarins, vincristine, vinblastine, paclitaxel and its analogues, methotrexate, cisplatin, fluorouracil, rapamycin, azathioprine, cyclophosphamide, mycophenolic acid, corticosteroids, colchicine, nitroprusside, paclitaxel, angiostatin and endostatin; genetic materials, oligonucleotides, Cilazapril, Lisinopril, Captopril, VEGF, FGF, Probucol, Tocopherol, nifedipine, dipyridamole, Molsidomine, angiopeptin, prednisolone, glucocorticoid, dexamethasone, rifamycin, Re-188, Re-186, I-125, Y-90 celecoxib, Vioxx, dipyridamole, and theophylline.

Claim 16 (currently amended): A method of making the device of claim 11 [4], comprising preparing a surface having open gas-trapping structures, and over-coating with a thin, flexible film enclosing the entrapped gas bubbles in the surface structures beneath the coating.

Claim 17 (currently amended): A method of visualizing a medical device according to claim 11 [4] in an ambient medium, comprising:

inserting the device into a tissue,

leaving the device in the tissue for a prolonged period,

then directing an ultrasound beam at the tissue, and observing the device in the tissue.

Claim 18 (currently amended): A method for increasing the echogenicity of an object when subjected to ultrasound in an ambient material, the method comprising the steps of:

providing a coating liquid comprising a film-forming constituent;

applying the coating liquid to the object;

allowing the film-forming constituent to form a film comprising a solid matrix; and providing the film with an echogenic structure presenting echogenicity-increasing gas/non-gas interfaces,

wherein the echogenic structure comprises a top coating over gas-trapping spaces, the top

coating having a water permeability of less than about 10<sup>-10</sup> [(cm<sup>3</sup>)(cm)]/(cm<sup>2</sup>)(s)(cm Hg)], and wherein providing the film with an echogenic structure comprises including in the coating liquid (a) gas bubbles, and/or (b) a reactive material that generates gas upon reaction with a reactor and further contacting the reactive material with the reactor to produce gas.

Claim 19 (cancelled).

Claim 20 (new): A device according to claim 12, wherein the needle is a biopsy needle.

Claim 21 (new): A device according to claim 8, wherein the structures are selected from the group consisting of pores, channels, cavities, pockets, and combinations thereof, covered by the overcoat.

Claim 22 (new): A device according to claim 8, wherein the overcoat incorporates one or more pharmaceutical agents.

Claim 23 (new): A device according to claim 8, wherein the overcoat layer reduces wettability so as to promote and/or prolong the entrapment of gas when the device is in the target medium.

Claim 24 (new): A device according to claim 8, wherein the overcoat layer has a thickness below about 2 microns.

Claim 25 (new): A device according to claim 8, wherein the overcoat layer has a thickness of between about 0.1 and about 1 micron.

Claim 26 (new): A device according to claim 8, comprising one or more of a pharmaceutical agent selected from the group consisting of anti-thrombogenic agents, anti-inflammatory agents, antineoplastic agents, anti-proliferative agents, cytostatic agents, cytotoxic agents, antimicrobial agents, anti-restenotic agents, anti-platelet agents, anti-coagulant agents, anti-fibrin and fibrinolytic agents, prostacyclins (and analogues), glycoprotein IIb/IIIa agents, thromboxane inhibitors, anti-thrombin agents, anti-mitotic, antiangiogenic and angiostatic agents, ACE inhibitors, growth factor antagonists, antioxidants, vitamins, calcium channel blockers, fish oil (omega 3-fatty acid), phosphodiesterase inhibitors, nitric acid donor, Somatostatin analogues, immunosuppresives and antiinflamatory agents, antimicrobials, radionuclides including alpha, beta and gamma emitting isotopes, COX-2 inhibitors, endothelial promoters, kinase inhibitors, epidermal growth factor kinase inhibitors, tyrosine kinase inhibitors, MAP kinase inhibitors, and protein transferase inhibitors.

Claim 27 (new): A device according to claim 8, comprising comprises one or more of a pharmaceutical agent selected from the group consisting of plasmin, streptokinase, single chain

urokinase, urokinase, t-PA (tissue type plasminogen activator), aminocaproic acid, aspirin, monoclonal antibodies, peptides, ReoPro, Cilastagel, eptifibatide, tirofiban, ticlopidine, Vapiprost, dipyridamole, forskolin, angiopeptin, argatroban, dextan, heparin, LMW heparin, Enoxaparin, Dalteparin, hirudin, recombinant hirudin, anti-thrombin, synthetic antithrombins, thrombin inhibitors, Warfarin, other coumarins, vincristine, vinblastine, paclitaxel and its analogues, methotrexate, cisplatin, fluorouracil, rapamycin, azathioprine, cyclophosphamide, mycophenolic acid, corticosteroids, colchicine, nitroprusside, angiostatin and endostatin; genetic materials, oligonucleotides, Cilazapril, Lisinopril, Captopril, VEGF, FGF, Probucol, Tocopherol, nifedipine, Molsidomine, angiopeptin, prednisolone, glucocorticoid, dexamethasone, rifamycin, Re-188, Re-186, I-125, Y-90 celecoxib, Vioxx, and theophylline.

Claim 28 (new): A device according to claim 8, wherein the device is a stent, central venous catheter, peripherally inserted catheter, graft, shunt, percutaneous transcardiac arterial catheter, pacemaker, dialysis device, joint replacement, long term urinary device, tissue bonding urinary device, penile prosthesis, vascular catheter port, peripherally insertable central venous catheter, long term tunneled central venous catheter, peripheral venous catheter, short term central venous catheter, arterial catheter, PCTA or PTA catheter, and pulmonary artery Swan-Ganz catheter, guidewire, a surgical instrument, endoscopy equipment, an angioplasty balloon, a wound drain, a gastroenteric tube, laparoscopy equipment, a pellet, and an implant, a needle, a biopsy needle, and combinations thereof.

Claim 29 (new): A device according to claim 9, wherein the structures are selected from the group consisting of pores, channels, cavities, pockets, and combinations thereof, covered by the overcoat.

Claim 30 (new): A device according to claim 9, wherein the overcoat incorporates one or more pharmaceutical agents.

Claim 31 (new): A device according to claim 9, wherein the overcoat layer reduces wettability so as to promote and/or prolong the entrapment of gas when the device is in the target medium.

Claim 32 (new): A device according to claim 9, wherein the overcoat layer has a thickness below about 2 microns.

Claim 33 (new): A device according to claim 9, wherein the overcoat layer has a thickness of between about 0.1 and about 1 micron.

Claim 34 (new): A device according to claim 9, comprising one or more of a

pharmaceutical agent selected from the group consisting of anti-thrombogenic agents, anti-inflammatory agents, antineoplastic agents, anti-proliferative agents, cytostatic agents, cytotoxic agents, antimicrobial agents, anti-restenotic agents, anti-platelet agents, anti-coagulant agents, anti-fibrin and fibrinolytic agents, prostacyclins (and analogues), glycoprotein IIb/IIIa agents, thromboxane inhibitors, anti-thrombin agents, anti-mitotic, antiangiogenic and angiostatic agents, ACE inhibitors, growth factor antagonists, antioxidants, vitamins, calcium channel blockers, fish oil (omega 3-fatty acid), phosphodiesterase inhibitors, nitric acid donor, Somatostatin analogues, immunosuppresives and antiinflamatory agents, antimicrobials, radionuclides including alpha, beta and gamma emitting isotopes, COX-2 inhibitors, endothelial promoters, kinase inhibitors, epidermal growth factor kinase inhibitors, tyrosine kinase inhibitors, MAP kinase inhibitors, and protein transferase inhibitors.

Claim 35 (new): A device according to claim 9, comprising comprises one or more of a pharmaceutical agent selected from the group consisting of plasmin, streptokinase, single chain urokinase, urokinase, t-PA (tissue type plasminogen activator), aminocaproic acid, aspirin, monoclonal antibodies, peptides, ReoPro, Cilastagel, eptifibatide, tirofiban, ticlopidine, Vapiprost, dipyridamole, forskolin, angiopeptin, argatroban, dextan, heparin, LMW heparin, Enoxaparin, Dalteparin, hirudin, recombinant hirudin, anti-thrombin, synthetic antithrombins, thrombin inhibitors, Warfarin, other coumarins, vincristine, vinblastine, paclitaxel and its analogues, methotrexate, cisplatin, fluorouracil, rapamycin, azathioprine, cyclophosphamide, mycophenolic acid, corticosteroids, colchicine, nitroprusside, angiostatin and endostatin; genetic materials, oligonucleotides, Cilazapril, Lisinopril, Captopril, VEGF, FGF, Probucol, Tocopherol, nifedipine, Molsidomine, angiopeptin, prednisolone, glucocorticoid, dexamethasone, rifamycin, Re-188, Re-186, I-125, Y-90 celecoxib, Vioxx, and theophylline.

Claim 36 (new): A device according to claim 9, wherein the device is a stent, central venous catheter, peripherally inserted catheter, graft, shunt, percutaneous transcardiac arterial catheter, pacemaker, dialysis device, joint replacement, long term urinary device, tissue bonding urinary device, penile prosthesis, vascular catheter port, peripherally insertable central venous catheter, long term tunneled central venous catheter, peripheral venous catheter, short term central venous catheter, arterial catheter, PCTA or PTA catheter, and pulmonary artery Swan-Ganz catheter, guidewire, a surgical instrument, endoscopy equipment, an angioplasty balloon, a wound drain, a gastroenteric tube, laparoscopy equipment, a pellet, and an implant, a needle, a biopsy needle, and combinations thereof.